NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LORY D'ADDARIO AND PETER D'ADDARIO, Plaintiffs, v. JOHNSON & JOHNSON, et al., Defendants.	Civil Action No. 19-15627 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court upon Defendants Mentor Worldwide, LLC ("Mentor"), Ethicon, Inc. ("Ethicon"), and Johnson & Johnson's (collectively, "Defendants") Motion to Dismiss Plaintiffs Lory D'Addario ("D'Addario") and Peter D'Addario's (collectively, "Plaintiffs") Amended Complaint. (ECF No. 36.) Plaintiffs opposed (ECF No. 39), and Defendants replied (ECF No. 41). A plethora of other filings followed. Plaintiffs filed a Motion for Leave to File a Sur-Reply in Opposition to Defendants' Motion to Dismiss, (ECF No. 44), Defendants opposed (ECF No. 45), and Plaintiffs replied (ECF No. 47). Defendants then filed a Notice of Supplemental Authority (ECF No. 49) and Plaintiffs replied (ECF Nos. 50, 51). Next, Defendants filed another Notice of Supplemental Authority (ECF No. 52), Plaintiffs again responded (ECF No. 53), and Defendants again replied (ECF No. 54). Finally, Plaintiffs filed their own Notice of Supplemental Authority (ECF No. 55), to which Defendants responded (ECF No. 56). The Court has carefully considered the parties' submissions and decides the matter without

oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Defendants' Motion is granted.

I. BACKGROUND

On June 14, 2013, the United States Food and Drug Administration ("FDA") approved Mentor's premarket approval application ("PMA") for its MemoryShape breast implants (hereinafter, "Mentor Breast Implants"). (Am. Compl. ¶ 77, ECF No. 32.) Defendants design, manufacture, market, label, and distribute Mentor Breast Implants. (*Id.* ¶ 217.)

The Mentor Breast Implants at issue in this case are "textured." (*Id.* ¶ 1.) With regard to the Mentor Breast Implants' textured surface, the Amended Complaint avers that

> Mentor uses negative-contact polyurethane foam to stamp its Siltex breast implant surfaces. Specifically, a chuck is dipped into uncured silicone to form the shell after which the uncured silicone shell is pressed into polyurethane foam to imprint pores measuring 70 to 150 mm in diameter and 40 to 100 mm in height.

(*Id.* ¶ 221 (citations omitted).) "This process causes 'shedding of surface debris.'" (*Id.* ¶1, *49 (citations omitted).)[1] Plaintiffs assert that the "'shedding of particulate matter' on the implant surface is a manufacturing defect that, at times, produces an adulterated dangerous and defective product violative of 21 C.F.R. § 820.70(h) and 21 U.S.C. § 351." (*Id.*) Plaintiffs maintain that "shedded silicone surface debris," when embedded in a patient, can be recognized by the body as foreign matter and trigger Breast Implant Associated Large Cell Lymphoma ("BIA-ALCL")." (*Id.* ¶¶ 1-3, *49.)

Plaintiffs allege that following the PMA for the Mentor Breast Implants, Defendants failed to comply with numerous FDA post-approval reporting requirements. For example, Plaintiffs assert that Defendants "failed to report adverse events, including incidences of BIA-ALCL, from

[1] Page numbers preceded by an asterisk refer to the page number on the ECF header. The Court notes that on *49-50, Plaintiffs' paragraph numbering appears to inadvertently repeat at ¶ 1.

the post-market approval studies commissioned [by the FDA] as part of the implant's PMA approval." (*Id.* ¶ 99.) With respect to these post-market approval studies, Plaintiffs maintain that "Mentor failed to properly perform the six studies, failed to follow-up with enough participants, and did not fully report adverse events. Accordingly, the information which the FDA was seeking regarding adverse events and device failures was never gathered." (*Id.* ¶ 43.) Plaintiffs note that "time is of the essence for Mentor when reporting adverse events, especially, but not limited to, those adverse events indicating an association between its product and breast cancer, Anaplastic Large-Cell Lymphoma ("ALCL") and/or BIA-ALCL." (*Id.* ¶ 85.) "Delayed reporting prevents the healthcare community and the public from learning of risks which must inevitably play a part in their decision-making, by both physicians and consumers, regarding treatments and procedures, and thereby expose[s] countless additional women to potential harm." (*Id.* ¶ 86.)

In July 2015, after a breast cancer diagnosis and subsequent mastectomy, D'Addario underwent breast reconstructive surgery and received Mentor Breast Implants. (*Id.* ¶ 193.) Plaintiffs allege that at that time, "Defendants were aware that Mentor Implants caused [BIA-ALCL]" but failed to advise D'Addario of the risk. (*Id.* ¶ 199.) Plaintiffs also allege that, had D'Addario known of even the slightest risk of developing ALCL and/or BIA-ALCL from the Mentor Breast Implants, she would not have proceeded with the implantation. (*Id.* ¶ 200.)

In July 2017, D'Addario tested positive for BIA-ALCL. (*Id.* ¶ 202.) Following diagnosis and treatment, D'Addario suffered pain, swelling, and embarrassment. (*Id.* ¶ 205.) In August 2017, D'Addario underwent implant removal and total capsulectomy. (*Id.* ¶ 159.)

According to Plaintiffs, "[t]he Mentor Breast Implants Mrs. D'Addario received were not the breast implants approved by the FDA as they contained non-conforming debris-laden defective implants." (*Id.* ¶ 232.) Plaintiffs assert that "Mentor failed to adhere to the specifications imposed

and intended by the FDA through the implants' PMA and thus manufactured defective implants containing particles and debris in violation of FDA [Quality System Regulations ("QSRs")] and [current good manufacturing processes ("CGMPs")], which caused [D'Addario's] BIA-ALCL." (*Id.* ¶ 233.)[2] The Amended Complaint maintains that Defendants' manufacturing deficiencies included: "manufacturing their textured breast implants in a non-conforming manner"; "failing to sterilize the implants in conformance with the PMA"; "failing to satisfy the study and follow-up requirements set forth in the PMA and other federal requirements"; "failing to maintain procedures to prevent contamination of equipment or products"; and "failing to timely and accurately submit adverse event reports on the occurrence of BIA-ALCL." (*Id.* ¶ 234.)

Plaintiffs bring two Counts against Defendants. Plaintiffs bring Count One for violation of the Connecticut Products Liability Act ("CPLA"), Conn. Gen. Stat. §§ 52-572m, *et seq.*, under manufacturing defect, breach of express and implied warranties, failure to provide warnings, negligent manufacturing, and negligent misrepresentation theories. (*Id.* ¶¶ 220-303.) Plaintiffs bring Count Two for loss of consortium. (*Id.* ¶¶ 304-08.)

II. LEGAL STANDARD

District courts undertake a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). "First, the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)) (alteration in original). Second, the court must accept as true all of the plaintiff's well-pled factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quotation omitted). In doing so, the court is free to ignore legal conclusions

[2] The FDA's CGMPs and QSRs are set forth in 28 C.F.R.§ 820, *et seq.*

or factually unsupported accusations that merely state "the-defendant-unlawfully-harmed-me." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[M]ere restatements of the elements of [a] claim[] . . . are not entitled to the assumption of truth." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 224 (3d Cir. 2011) (alterations in original) (quotation omitted). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citation omitted).

"Rule 12 prohibits the court from considering matters outside the pleadings in ruling on a motion to dismiss for failure to state a claim . . . and a court's consideration of matters outside the pleadings converts the motion to a motion for summary judgment." *Kimbugwe v. United States*, No. 12-7940, 2014 WL 6667959, at *3 (D.N.J. Nov. 24, 2014). "[A]n exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis omitted) (internal quotation marks omitted). Notwithstanding these principles, courts may not consider claims raised for the first time in a plaintiff's opposition to a motion to dismiss. *See Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." (internal quotation omitted)).

III. DISCUSSION

A. Federal Preemption

It is undisputed that the Mentor Breast Implants at issue in this litigation are a Class III medical device approved by the FDA under the premarket approval process outlined by the

Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). (Am. Compl. ¶¶ 32-35.) "Before marketing a Class III medical device, the manufacturer must submit a PMA application that the FDA can grant 'only after it determines that a device offers a reasonable assurance of safety and effectiveness.'" *In re Allergan Biocell Textured Breast Implant Prods. Liability Litig.*, No. 19-2921, 2021 WL 1050910, at *7 (D.N.J. Mar. 19, 2021) (Martinotti, J.) (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (citing 21 U.S.C. § 360e(d))). "A state law product liability or tort claim relating to a medical device may be expressly or impliedly preempted by the MDA," which "contains a broad express preemption provision." *Id.* (quoting *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 767 (3d Cir. 2018)). "The MDA provides that no State 'may establish or continue in effect *with respect to a device . . . any requirement*' relating to safety or effectiveness that is different from, or in addition to, federal requirements." *Riegel*, 552 U.S. at 328 (emphasis in original) (quoting 21 U.S.C. § 360k(a)).

The Supreme Court has recognized, however, a narrow exception for a "'parallel' claim, *e.g.*, 'a damages remedy for claims premised on a violation of FDA regulations.'" *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 600 (D.N.J. 2015) (quoting *Riegel*, 552 U.S. at 330). To determine whether the MDA expressly preempts a state claim under § 360k(a), courts consider (1) whether the FDA has established "requirements" applicable to the specific device at issue; and if so, (2) whether the plaintiff's claims are based on state requirements that are "different from, or in addition to," the federal ones and that "relate to safety and effectiveness." *Shuker*, 885 F.3d at 771 (citing *Riegel*, 552 U.S. at 321-22). If the answer is yes to both questions, the state claim is preempted. *Id.* "If, instead, the answer to the second question is no, then the state duties in such a case parallel, rather than add to, federal requirements, and the claims are not preempted." *Id.* (citation omitted) (internal quotation marks omitted).

Even if a state-law claim is not expressly preempted, it may be impliedly preempted under § 337(a). Under the MDA, all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "[T]he Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). To that end, the *Buckman* Court held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and are impliedly preempted by the MDA. *Id.* at 350.

Ultimately, where a state-law claim for violating a state-law duty "parallels" a federal-law duty under the MDA, the MDA will not preempt the state-law claim. *Riegel*, 552 U.S. at 330. It is not enough to state that a state law parallels federal law generally. Plaintiffs must also allege a link between a product's deviation from an FDA requirement and the alleged injury. *Clements*, 111 F. Supp. 3d at 598; *see Simoneau v. Stryker Corp.*, No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (dismissing a plaintiff's misbranding, failure to warn, and failure to report claims for failure to link her injury to a violation of an FDA requirement).

The Court considers Plaintiffs' claims within the foregoing legal framework.

1. Manufacturing Defect

"To sufficiently plead a manufacturing defect claim, [p]laintiffs must allege [defendants] 'deviated from a particular premarket approval or other FDA requirement applicable to the class III medical device[.]'" *In re Allergan*, 2021 WL 1050910, at *20 (quoting *Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 WL 406304, at *2 (9th Cir. Feb. 5, 2021)). Moreover, Plaintiffs "cannot simply demonstrate a defect or a malfunction and rely on *res ipsa loquitur* to

suggest only . . . that the thing speaks for itself." *Id.* (alterations in original) (quoting *Nunn*, 2021 WL 406304, at *2).

As discussed above, Plaintiffs may bring state law tort claims against Defendants that "parallel" a violation of FDA regulations. Nevertheless, courts "use the *Iqbal/Twombly* standard to determine whether [p]laintiffs have stated a plausible claim" for manufacturing defect. *Brooks v. Mentor Worldwide, LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021); *see also Morton v. Allergan, Inc.*, No. 14-1312, 2015 WL 12839493, at *4 (D.N.J. Apr. 2, 2015) ("[i]n short, a 'parallel claim,' like any other, is subject to the pleading standards of *Twombly*"). "Plaintiffs must nudge the claim across the line from conceivable or speculative to plausible. Allegations that are merely consistent with a defendant's liability stop short of that line." *Brooks*, 985 F.3d at 1281 (citations omitted). Courts have emphasized that a plaintiff "cannot simply incant the magic words [the defendant manufacturer] violated FDA regulations in order to avoid preemption." *Morton*, 2015 WL 12839493, at *4 (citations omitted). "Rather, the plaintiff must plead facts showing action or inaction in [the] defendants' efforts to take part in the PMA process or implement its results." *Clements*, 111 F. Supp. 3d at 599 (alteration in original) (citation omitted).

Here, Plaintiffs allege that Defendants violated several of the FDA's Current Good Manufacturing Practices ("CGMPs") regulations governing the manufacturing of medical devices. (*See, e.g.*, Am. Compl. ¶ 116 (alleging Defendants violated 21 C.F.R. § 820.70(h) (requiring manufacturers to "establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not affect the device's quality")); *id.* ¶ 81(d) (alleging Defendants violated 21 C.F.R. § 820.70(e) (requiring manufacturers to "establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product

quality")).) The Court agrees with Plaintiffs that these allegations *potentially* set forth a state-law claim based on a violation of federal law that would fall within the "parallel claim" exception to preemption. *Accord with Morton*, 2015 WL 12839493, at *5. "To survive preemption," however, the plaintiff must not "simply provide a laundry list of alleged CGMP violations, which is too general to be capable of enforcement." *In re Allergan*, 2021 WL 1050910, at *13 (internal quotation marks and citations omitted). Without more, Plaintiffs' citation to regulations alone would "offer little more than 'labels and conclusions.'" *Morton*, 2015 WL 12839493, at *5 (quoting *Twombly*, 550 U.S. at 555). The key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs but rather "a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." *Bass v. Stryker Corp.*, 669 F.3d 501, 511-12 (5th Cir. 2012) (emphasis in original).

Plaintiffs offer the following additional factual assertions about the Mentor Breast Implants in support of their manufacturing defect claims:

> Mentor uses negative-contact polyurethane foam to stamp its Siltex breast implant surfaces. Specifically, a chuck is dipped into uncured silicone to form the shell after which the uncured silicone shell is pressed into polyurethane foam to imprint pores measuring 70 to 150 mm in diameter and 40 to 100 mm in height.

(Am. Compl. ¶ 221 (citations omitted).) "This process causes 'shedding of surface debris[.]'" (*Id.* 1 ¶, *49 (citations omitted).) Plaintiffs assert that this "'shedding of particulate matter' on the implant surface is a manufacturing defect that, at times, produces an adulterated dangerous and defective product violative of 21 C.F.R. § 820.70(h) and 21 U.S.C. § 351." (*Id* 2 ¶, *49.) Nevertheless, the above facts do not assert which, if any part, of the above-described processes deviated from the manufacturing processes approved by the FDA.

Moreover, while the above-described process may well contribute to the shedding that caused D'Addario's injuries, nothing in this recitation suggests a manufacturing defect rather than a *design* defect. For example, Plaintiffs do not assert facts establishing that the shedded material is a "manufacturing material" that Defendants were required to limit or sterilize pursuant to Section 820. *See* 21 C.F.R. § 820(h). FDA regulations provide that where a "manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." *Id.* A "manufacturing material" means "any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device *as a residue or impurity not by design or intent of the manufacturer*." 21 C.F.R. § 820.3(p) (emphasis added). Aside from Plaintiffs' conclusory allegation that the shedded material was "residual debris," (Am. Compl. ¶ 49), nothing in the Amended Complaint suggests that the shedded material was "residual" within the meaning of Section 820.3 and 820(h), as opposed to being a function of the device's textured design approved by the FDA. *Cf. Canary v. Medtronic, Inc.*, No. 16-11742, 2017 WL 1382298, at *10 (E.D. Mich. Apr. 18, 2017) ("Nothing in [p]laintiff's first amended complaint suggests that the manufacturing process used by [d]efendant generated any such . . . residue or impurity that was subject to removal under the CGMP." Rather, "the manual . . . expressly discloses that parts of this device contain silicone rubber or silicone medical adhesive . . . and the intentional use of these materials in [d]efendant's device disqualifies them from consideration as 'manufacturing materials' that must be reduced or removed from the device.").

Federal courts across the country have granted Rule 12(b)(6) motions alleging manufacturing defects in Mentor Breast Implants for similar failures. *See, e.g.*, *Brooks v. Mentor Worldwide, LLC*, 985 F.3d 1272, 1281-82 (10th Cir. 2021) ("these factual allegations do not touch on any specific flaw in the manufacturing process relevant to [p]laintiffs' own implants. Nor does [p]laintiffs' . . . [c]omplaint describe a particular flaw in the specific implants they received"); *Nunn*, 2021 WL 406304, at *2 (rejecting manufacturing defect claims because "[p]laintiffs fail to allege that [Mentor] violated a particular FDA requirement[,]" and while "[p]laintiffs vaguely allege that Mentor's MemoryGel Silicone Breast Implants contained unidentified materials that differed from those approved by the FDA," those allegations "do[] not show that [Mentor] failed to comply with the FDA's [CGMPs]."); *Ebrahimi v. Mentor Worldwide, LLC*, 2018 WL 6829122, at *1-2 (C.D. Cal. Dec. 27, 2018) (dismissing manufacturing defect claims allegedly arising from Mentor breast implant products where the complaint failed to "purport to announce the FDA's manufacturing specifications" and finding that "a complaint must include *specific allegations* that the manufacturing of the device . . . fell short of the *FDA's requirements for manufacturing*") (alteration in original) (emphasis in original) (citations omitted)), *aff'd*, 804 F. App'x 871 (9th Cir. 2020) ("Mentor's [p]roduct [i]nsert [d]ata [s]heet does not reflect that the FDA-approved implants had some design specification or manufacturing requirement that would only allow an extremely low level of gel bleed with no clinical consequence." (citations and internal quotation marks omitted)). Once again, Plaintiffs "cannot simply demonstrate a defect or a malfunction and rely on *res ipsa loquitur* to suggest only . . . that the thing speaks for itself." *In re Allergan*, 2021 WL 1050910, at *20 (alterations in original) (quoting *Nunn*, 2021 WL 406304, at *2). "[E]ven if more general FDA requirements are sufficient for a parallel claim, mere allegations suggesting that

[plaintiff's] particular breast implant[s] w[ere] defective do[] not show that [Mentor] failed to comply with the FDA's [CGMPs]." *Ebrahimi*, 804 F. App'x at 872 (citations omitted).

In re Allergan is illustrative. Similar to this case, the plaintiffs there alleged that the defendant's "textured implants increase the risk of BIA-ALCL by 3,000 times." *In re Allergan*, 2021 WL 1050910, at *3. The plaintiffs connected their injuries to a specific defect in Allergan's breast implant manufacturing process:

> To texturize the implant shell, Allergan allegedly employed a "salt loss" manufacturing process. The process applies solid particles of cubic salt over the implant shell surface, embedding the particles within. The implant is then covered with another silicone layer, which is scrubbed off, and the shell is washed. Plaintiffs state the FDA-approved manufacturing specifications require all solid particles be scrubbed off and dissolved. Plaintiffs allege Allergan performs the final scrubbing process manually, which leaves solid particles and other residues on the implants' surface. Plaintiffs claim these particles, residues, the implant's increased surface area resulting from the texturizing process, and the chronic friction that occurs between the body's tissues and the implant cause inflammation, increased T-cell activity, malignant T-cell transformation and, ultimately, BIA-ALCL.

Id. The plaintiffs in *In re Allergan* plainly alleged that the FDA requires the particles at issue to be scrubbed or dissolved off of the implant's surface and that the defendant nevertheless leaves these residues on the surface.

Here, by contrast, Plaintiffs have not alleged actions or inactions by Defendants that deviate from the manufacturing process approved by the FDA. "Although a complaint need not contain detailed factual allegations, 'a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions.'" *Morton*, 2015 WL 12839493, at *2 (quoting *Twombly*, 550 U.S. at 555). "The factual allegations must be sufficient to raise a plaintiff's right to relief beyond the merely speculative level to demonstrate that the claim is 'plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "This requires the plaintiff to plead 'factual

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* (quoting *Iqbal*, 556 U.S. at 662). Plaintiffs' conclusory pleadings describing the shedded material as "residual debris" fail to meet this standard.

2. Failure to Warn

Plaintiffs also allege that Defendants failed to adequately warn "Plaintiff and/or Plaintiff's implanting physician about the dangers of Mentor's Breast Implants, and about all adverse events of which Mentor became aware, and had a post-market duty to identify, monitor and report[.]" (Am. Compl. ¶ 120.) Plaintiffs allege that Defendants failed to properly perform a number of studies required by the FDA as a condition for approving the PMA. (*Id.* ¶¶ 42-43.) Plaintiffs maintain that Defendants failed to attain the participation rates that would have been "sufficient to allow for the identification of problems and adverse effects from long term use of the product." (*Id.* ¶ 56.) Because Defendants allegedly failed in this regard, Plaintiffs maintain that important adverse event data was never reported to the FDA. (*Id.* ¶ 75 ("Had Mentor properly performed its required studies and reported the multitude of captured adverse events, the FDA would have included the adverse events in the MAUDE database.").)

Other courts have rejected similar claims as inadequately pled:

> Plaintiffs' failure to warn claims are primarily based on Mentor's alleged failure to report adverse events related to its MemoryGel Silicone Breast Implants to the FDA . . . . Plaintiffs fail to allege actual adverse events that Mentor did not report to the FDA. Rather, [p]laintiffs speculate that if Mentor had conducted its post-approval studies differently (e.g., increased follow-up with participants), then Mentor would have identified additional adverse events that it would have reported to the FDA. These conclusory and speculative allegations are insufficient to state a parallel failure to warn claim.

Nunn, 2021 WL 406304, at *2 (citing *Twombly*, 550 U.S. at 555); *Vieira v. Mentor Worldwide, LLC*, No. 19-56394, 2021 WL 406628, at *2 (9th Cir. Feb. 5, 2021). Furthermore, the Court notes that although the Honorable Brian R. Martinotti, U.S.D.J., recently denied a motion to dismiss

failure to warn claims in *Allergan*, the allegations there are distinguishable from the case at bar. *Allergan* involved a failure to warn claim where *known* adverse event information was allegedly improperly submitted. *In re Allergan*, 2021 WL 1050910, at *10 (noting that the plaintiffs challenged "Allergan's improper submission to the FDA of Alternative Summary Reports . . . rather than Medical Device Reports . . . which contain a full narrative description of the event and are published in the FDA's MAUDE database every month"); *see also* Complaint ¶ 35, ECF No. 119, *In re Allergan*, No. 19-2921 (D.N.J. May 26, 2020) (alleging that "Allergan had information showing that its Biocell implants were associated with BIA-ALCL for years prior to submitting its first MAUDE report to the FDA . . . . Allergan conceded that it had received 104 reports of confirmed, suspected, and pending confirmation ALCL cases associated with a textured breast implant between at least 2007 and 2015").

Because the Court finds the Ninth Circuit's opinions in *Nunn* and *Vieira* persuasive, and because Judge Martinotti's opinion in *Allergan* is distinguishable, the Court will grant Defendants' Motion to Dismiss the failure to warn claims.

3. Breach of Express and Implied Warranties and Negligent Misrepresentation

Plaintiffs allege that Defendants breached express and implied warranties by selling "defective [b]reast [i]mplants as though they ha[d] met all federal requirements." (Am. Compl. ¶ 252.) Similarly, Plaintiffs allege that Defendants "knowingly made negligent misrepresentations of fact by selling its [b]reast [i]mplants that were defectively manufactured as if they were manufactured pursuant to all federal specifications." (*Id.* ¶ 295.)

Here, Plaintiffs' negligent misrepresentation and express and implied warranty claims "have a common theme—[d]efendants misrepresented that [defendant's device] was safe—which directly contradicts the FDA's finding that the [device] is safe and effective, a determination made

in the PMA process." *Smith v. Depuy Orthopaedics, Inc.*, No. 11-4139, 2013 WL 1108555, at *11 (D.N.J. Mar. 18, 2013). "Because these allegations question the safety of the device and would require the Court to find that Defendants misrepresented that the device was safe and effective to succeed, they are preempted." *Id.*

With respect to implied warranties specifically, courts in this District have held that "if a manufacturer complies with the premarket approval, it gets a free pass on [products liability and implied breach of warranty] claims." *Banner v. Cyberonics, Inc.*, No. 08-741, 2010 WL 455286, at *3 (D.N.J. Feb. 4, 2010) (alterations in original) (citation omitted). Relatedly, "an express warranty claim is not preempted insofar as it is based on voluntary statements, i.e., statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product." *Morton*, 2015 WL 12839493, at *5.

The Amended Complaint currently before the Court does not identify voluntary statements about the use or effectiveness of the Mentor Breast Implants that were not approved by the FDA. *Compare with id.* ("Morton's [c]omplaint does not factually allege that Allergan made any voluntary statement regarding the safety of the LAP-BAND that was not approved by the FDA. Count VII is therefore preempted as well."). And as discussed in Section III.A.1 above, the Amended Complaint does not identify manufacturing defects that would create a breach of Defendants' implied warranty that the Mentor Breast Implants did not deviate from the manufacturing processes approved by the FDA. Accordingly, the breach of express and implied warranty claims are preempted by federal law.

4. Negligent Manufacturing

Plaintiffs allege that Defendants were "negligent in manufacturing its breast implants without controlling the texturing process leaving silicone particles, debris[,] and fragments from

the textured elastomer shell on the implant surface." (Am. Compl. ¶ 286.) By approving the PMA, however, "the FDA determined that the [Mentor Breast Implant's] manufacture, design, and warnings were safe and effective." *Morton*, 2015 WL 12839493, at *4. Accordingly, Plaintiff's negligent manufacture claim is preempted "because [it] assert[s] 'general tort duties of care,' allege[s] that 'a device was . . . manufactured in an unsafe or ineffective manner,' and imposes different or additional requirements related to the safety and effectiveness" of the device. *Delaney v. Stryker Orthopaedics*, No. 08-3210, 2009 WL 564243, at *3 (D.N.J. Mar. 9, 2009) (quoting *Riegel*, 128 S. Ct. at 1010). Once again, Plaintiffs identify no deviations from the manufacturing process approved by the FDA. *See* Section III.A.1. As such, Plaintiffs fail to state a negligent manufacturing claim that parallels the FDA's regulations and survives the Defendants' preemption challenge.

B. Loss of Consortium

As the Court previously held, because a loss of consortium claim is a derivative claim, and because Plaintiffs fail to state a CPLA claim, their loss of consortium claim fails as a matter of law and must be dismissed. *D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 WL 3546750, at *6 (D.N.J. June 30, 2020).

IV. CONCLUSION

For the reasons set forth above, the Court grants Defendants' Motion to Dismiss. The Amended Complaint is dismissed without prejudice. The Court will provide Plaintiffs one final opportunity to amend their pleading and will set forth the deadline to file a second amended complaint in the accompanying Order.

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE